



---

Food and Drug Administration  
Rockville, MD 20857

April 6, 2004

Tish Treherne  
Philips Medical Systems  
2301 Fifth Avenue  
Suite 200  
Seattle, Washington 98121-1825

Dear Ms. Treherne:

Your petition requesting the Food and Drug Administration for an exemption from the medical device tracking requirements for Heartsteam automated external defibrillators, was received by this office on 04/06/2004. It was assigned docket number 2004P-0164/CP1 and it was filed on 04/06/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler, Director  
Division Of Dockets Management  
Office of Management Programs  
Office of Management

